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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,480	02/26/2004	Daniel P. Silver	20363-011 CON	8561

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Ivor R. Elrifi  
MINTZ, LEVIN, COHN,  
FERRIS, GLOVSKY AND POPEO, P.C.  
One Financial Center  
Boston, MA 02111

EXAMINER

SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 01/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/789,480	<b>Applicant(s)</b> SILVER ET AL.	
	<b>Examiner</b> Daniel M. Sullivan	<b>Art Unit</b> 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### **DETAILED ACTION**

Claims 1-34, as originally filed, are pending.

#### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1 and 2, drawn to a transgenic non-human animal comprising a cell comprising a nucleic acid molecule comprising first and second signal sequences positioned to mediate excision or inversion of a portion of a recombinase gene, classified in class 800, subclass 13.
- II. Claims 3-5, drawn to a transgenic plant comprising a cell comprising a nucleic acid molecule comprising first and second signal sequences positioned to mediate excision or inversion of a portion of a recombinase gene, classified in class 800, subclass 295.
- III. Claims 6-11 and 17-25, drawn to a method for modulating a target gene in a cell comprising introducing a first nucleic acid molecule into a cell wherein said first and second nucleic acid molecule are configured such that a recombinase encoded by the first nucleic acid molecule excises a sequence in said second nucleic acid molecule to modulate expression of a target gene, wherein the cell is in an animal, classified in class 435, subclass 455.
- IV. Claims 6 and 12-25, drawn to a method for modulating a target gene in a cell comprising introducing a first nucleic acid molecule into a cell wherein said first and second nucleic acid molecule are configured such that a recombinase encoded

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by the first nucleic acid molecule excises a sequence in said second nucleic acid molecule to modulate expression of a target gene, wherein the cell is in a plant, classified in class 435, subclass 455.

V. Claims 26-33, drawn to a cell comprising a first and second nucleic acid molecule configured to mediate strand exchange between the first and second nucleic acid molecules and a method of modulating a target gene in the cell, classified in class 435, subclass 325.

VI. Claim 34, drawn to a library of cells comprising a long terminal repeat and a recombinase recognition sequence integrated into the genome of each of the cells, classified in class 435, subclass 325.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are distinct. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to a transgenic non-human animal (Group I) and a transgenic plant (Group II), which are highly divergent biological entities that clearly have different modes of operation, function and effect.

Likewise, the methods of Groups III and IV, to the extent that they are directed to methods of using a non-human animal (Group III) or plant (Group IV), have different modes of operation, function and effect as a consequence of the distinct biological material used in each method.

Claim 6 link(s) inventions III and IV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 6. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The products and methods of Groups I/II, III/IV, V and VI are distinct, each from the other, in being directed to products and methods of using cells comprising distinctly configured nucleic acid molecules. For example, the nucleic acid comprised in the cells of the transgenic animal or plant of groups I and II comprises first and second signal sequences positioned to mediate excision or inversion of a portion of a recombinase gene, while the nucleic acid molecules of the other claims are not limited to being so configured. Likewise, the nucleic acids of Groups III and IV are configured such that a recombinase encoded by the first nucleic acid molecule excises a sequence in said second nucleic acid molecule to modulate expression of a target gene, the nucleic acid molecule of Group V is configured to mediate strand exchange between a first and second nucleic acid molecule and the nucleic acid of Group VI comprises a long terminal repeat, which configurations are unique to the nucleic acid of each Group.

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As the products and processes are distinct and therefore might be disclosed independently of one another, a search and examination of the inventions together in a single application would constitute an undue burden on the Office. Therefore, because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, or because each of the distinct Inventions comprise distinct elements and therefore cannot be searched coextensively, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M. Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 6:30-3:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel M Sullivan, Ph.D.  
Examiner  
Art Unit 1636

1/4/05

  
**DANIEL M. SULLIVAN**  
**PATENT EXAMINER**